Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Lot 1401-1403 T4; Lot 1511-1513 TSH; Lot 1551-1553 17-OHP
Set 2 - July 13, 2015

T4, TSH and 17-OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Thyroxine (T_4 µg/dL serum)	1401	2	1402	7	1403	11	October 31, 2016
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	1511	25	1512	40	1513	80	March 31, 2017
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	1551	25	1552	50	1553	100	March 31, 2017

ANALYTICAL INFORMATION

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Expiration Date*
T_4	1401	$\bar{x}$ = 1.8 CL = 1.4-2.2	1402	$\bar{x}$ = 6.4 CL = 5.5-7.2	1403	$\bar{x}$ = 11.0 CL = 9.3-12.7	October 31, 2016
TSH	1511	$\bar{x}$ = 27.1 CL = 23.5 – 30.6	1512	$\bar{x}$ = 48.9 CL = 42.1 – 55.6	1513	$\bar{x}$ = 90.5 CL = 75.0 – 106.1	March 31, 2017
17-OHP	1551	$\bar{x}$ = 23.7 CL = 19.2 - 28.2	1552	$\bar{x}$ = 47.7 CL = 39.1 - 56.4	1553	$\bar{x}$ = 97.7 CL = 83.0 - 112.5	March 31, 2017

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements.

Reference: *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In:Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*

Newborn Screening Quality Assurance Program

Hormones Quality Control Specimen Certification
Lot 1411-1413 TSH
Lot 1351-1353 17-OHP
July 13, 2015
Previous Lot Transition Materials (parallel testing)

T4, TSH and 17-OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Thyroxine (T_4 μg/dL serum)							
Thyroid-Stimulating Hormone (TSH μIU/mL serum)	1411	25	1412	40	1413	80	July 31, 2016
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	1351	25	1352	50	1353	100	September 30, 2015

ANALYTICAL INFORMATION

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Expiration Date*
T_4							
TSH	1411	$\bar{x}$ = 25.3 CL = 21.7 – 29.0	1412	$\bar{x}$ = 42.4 CL = 36.1 – 48.7	1413	$\bar{x}$ = 86.3 CL = 74.6 – 97.9	July 31, 2016
17-OHP	1351	$\bar{x}$ = 21.0 CL = 16.4 – 25.8	1352	$\bar{x}$ = 44.6 CL = 36.3 – 53.0	1353	$\bar{x}$ = 87.9 CL = 69.4 – 106.4	September 30, 2015

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements.

Reference: *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In:Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*